

Remarks

This communication is in response to the Office Action dated **March 10, 2005** wherein claims 34, 35, 37, 42-45 and 47 were rejected and/or objected to.

The specific rejections/objections are discussed in greater detail below and are addressed in the same order and with paragraph headings which correspond to the Final Office Action.

Applicant has included herewith new claims 48 and 49. The claims are believed to contain no new matter and are fully supported by the Application as originally filed.

Notice

In addition to the discussion presented below, Applicant submits herewith notice to the USPTO that the present Application, and/or related Applications and patents, is currently the subject of, or relevant to litigation. More specifically, a litigation is underway in the United States District Court for the Central District of California (Eastern Division-Riverside) involving G. David Jang verses Boston Scientific Corporation and Scimed Life Systems, Inc. (Civil Action Number: 05-00426). A litigation is also underway in the United States District Court for the District of Delaware between Boston Scientific Scimed Inc., and Boston Scientific Corporation verses Cordis Corporation and Johnson and Johnson Inc. (Civil Action Number: 03-283-SLR).

Claim Objections

In the Office Action claims 34, 35, 37 and 42-45 were objected to because the claims state that the stent has a tapered configuration in the expanded state, but in the Examiner's view only "each annual element" (sic) can have an expanded state and thus the expanded state of the stent lack antecedent basis.

Applicant has consistently responded to this rejection by pointing out to the Examiner that in a meeting between Applicant's representative Jonathan Grad, and Supervisory Examiner McDermott on December 18, 2003, Supervisory Examiner McDermott stated that the antecedent basis objection rejection is not necessary as the claim is understandable. It is therefore, the Applicant's position that given the Supervisory Examiner's view on this matter, it is unnecessary for the Applicant to amend the claims in response to an unnecessary objection.

In light of the opinion of the Supervisory Examiner on this matter, Applicant respectfully request that the objection be withdrawn. A copy of the Interview Summary prepared by Supervisory Examiner McDermott is enclosed.

Claim Rejections Based Upon Prior Art

U.S. 6,348,065 to Brown

In the Office Action claims 34, 35, 42, 43, 44 and 47 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 6,348,065 to Brown et al (Brown) or in the alternative under 35 U.S.C. §103(a) as being obvious over Brown.

In the Office Action the Examiner asserts that the stent of Brown has ends with different flexibilities than the middle portions, and that Brown further discloses a tapered configuration as claimed.

In response, Applicant asserts that Brown does not disclose a stent having a tapered configuration as claimed herein.

Throughout the prosecution of the instant Application, the Examiner has repeatedly pointed to FIG. 4, wherein various regions of the stent where struts come together appear to have a thinner width. The Examiner has viewed this feature of FIG. 4 as being within the scope of the meaning of the term “tapered configuration” as used in the instant claims. It is the Applicant’s position, that not only is this definition of “tapered configuration” inappropriate to describe the Brown stent, but it is clearly far beyond the ordinary definition of the term “tapered configuration” recognized by one of ordinary skill in the art and as defined by the present Application.

It is a fundamental principle of patent law that claim terms "are examined through the viewing glass of a person skilled in the art". *Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1338 (Fed. Cir. 2003). Furthermore, the person of ordinary skill in the art is deemed to have read the claim term(s) not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. *Multiform Desiccants, Inc. v. Medzam. Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998).

In the present Application the concept of a “taper” or tapered configuration is fully and clearly described on page 15, line 4 through page 16, line 11 of the original specification. In

the specification the term “taper” or “tapered configuration” is given a specific meaning referring to a change in the diameter and circumference of a stent along its length or a portion thereof. The definition and scope of the term “tapered configuration” as assigned by the Examiner however, is simply beyond the scope of the Application and not in keeping with its ordinary usage in the context of the claims.

As initially discussed on page 15 of the Application as originally filed, a stent is said to be provided with “a gradual taper from proximal end 12 to distal end 14” via the removal of selected segments of the expansion columns shown. The “shortened expansion struts 28”, which are shortened as a result of the removal of the selected segments, provide the affected portions of the stent with a tapered diameter portion having a “shortened circumference and diameter”. This “tapered diameter portion can be positioned anywhere along the length of the stent.” It is clear based on this description that a taper or a tapered configuration refers to a stent or portion thereof with a gradually tapered diameter and circumference along its length.

The description goes on, in the paragraph starting at line 18 of page 15, to describe the concept of providing a stent with a tapered diameter along its length in order to better accommodate different diameters of the vessel within which the stent is deployed. Once again the description of a tapered configuration is clearly in reference to a stent or portion thereof with a gradually tapered diameter along its length.

The next paragraph, starting at line 27 of page 15, does indeed refer to providing a stent with a tapered configuration by modifying characteristics, such as the width, of connecting struts, expansion struts, etc. This paragraph however is not to be read in a vacuum, in order to impose some meaning of the term “taper” that is not within, or contrary to, the scope of the term otherwise provided by the Application as a whole. See *Phillips v. AWH Corp.* 03-1269-1286 (Fed. Cir. 2005) (en banc) citing: *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005) (“We cannot look at the ordinary meaning of the term in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history.”); *V-Formation, Inc. v. Benetton Group*, 401 F.3d 1307, 1310 (Fed. Cir. 2005) (intrinsic record “usually provides the technological and temporal context to enable the court to ascertain the meaning of the claim to one of ordinary skill in the art at the time of the invention”); *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1351 (Fed. Cir. 2004) (proper

definition is the "definition that one of ordinary skill in the art could ascertain from the intrinsic evidence in the record").

In the context of the preceding paragraphs, the term "tapered configuration" is most certainly not referring to a stent which merely happens to have one or more struts whose width in one area is less than in another area, as the Examiner continues to assert. Instead, one of ordinary skill in the art would recognize that this paragraph merely provides one mechanism for providing a stent, or portion thereof, whose diameter is made to increase/decrease along the length of the stent (i.e. a tapered configuration) by modifying struts in the manner described. Without the change in diameter along its length, the stent, regardless of the characteristics of the struts, does not have a tapered configuration as described by the present claims and supporting specification.

This understanding of the term "tapered configuration" is further reinforced by the next two paragraphs beginning on line 1 of page 16, wherein the use of a tapered balloon in delivering a "tapered diameter stent" and/or imposing a tapered configuration on to a non-tapered stent is described.

As is illustrated by the above analysis of the written description as originally filed, it is intuitively obvious that the term "tapered configuration" refers to a stent which has a diameter that increases/decreases along its length or a portion thereof. Nowhere in the specification, drawings or elsewhere in the instant Application, or the Brown reference, could one of ordinary skill in the art reasonably impose a meaning on the term "tapered configuration" which refers exclusively to a change in width of a strut or struts of a stent that Examiner has attempted to impose based on the Brown reference.

Because Brown does not teach or suggest a stent having all of the elements of the instant claims, particularly a stent having a tapered configuration, the rejections based on §102 and §103 are respectfully traversed.

U.S. 5,716,393 to Lindenberg

In the Office Action claims 34, 35, 42-44 and 47 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 5,716,393 to Lindenberg et al (Lindenberg) or in the alternative under 35 U.S.C. §103(a) as being obvious over Lindenberg.

In the Office Action the Examiner states that “Lindenberg discloses a stent made from a single piece of material...having ends with different flexibilities than the middle portions...the tapered configuration as claimed is at both ends.”

In previous Office Actions the Examiner has acknowledged the fact that Lindenberg, fails to teach a stent having first and second ends that have different degrees of flexibility as the instant claims recite (see the Office Action of May 20, 2004) As the prosecution history will show, no amendments have been made to this language subsequent to the May 20 2004 Office Action. In addition, in the most recent Office Action the Examiner states: “Although the rejections of non-final Office action of May 2004 were found untenable, the conferees thought that at least some of the claims were not patentable based upon Lindenberg et al because *the end flexibilities do not have to be different from each other only from the rest of the stent*” (emphasis added) Despite this statement, nowhere in the Office Action does the Examiner identify those claims which he (or the “conferees”) concluded did not require ends which had different flexibilities from each other.

Applicant asserts that all of the instant claims describe stents having a first end with a different flexibility than the second end.

Applicant respectfully directs the Examiner to independent claims 34 and 42, wherein each of claim recites, in part: “wherein the first and second ends [of the stent] have different degrees of flexibility”. As to instant claim 47, the claim states, in part: “wherein the end-most annular element at the first end has a different degree of flexibility than the end-most annular element at the second end”. Applicant asserts that this language is clear and fully descriptive of the element of ends of the stent having different degrees of flexibility from one another. This feature, as been previously recognized by the Examiner, is not taught or suggested by Lindenberg. As a result the rejection is traversed.

U.S. 6,027,526 to Limon

In the Office Action claims 34, 35, 37, 42-45 and 47 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. 6,027,526 to Limon. In response, Applicant directs the Examiner to the detailed description of the term tapered configuration as set forth in the instant Application and the discussion of said term presented above.

In light of the above it is clear that while Limon does provide for struts of gradually increased thickness as shown in FIGs. 15-18, nowhere does Limon teach or suggest that the stents shown have a "tapered configuration" as the instant claims describe. In FIG. 17 for example, a stent is shown which has a uniform inner diameter throughout the entire length of the stent. It is unclear how such a stent could be considered to have a tapered configuration in accordance with the definition provided by the instant Application and its ordinary usage. Thus, the rejection is respectfully traversed.

CONCLUSION

In view of the foregoing it is believed that the present application, with claims 34, 35, 37, 39, 40, 42-45 and 47-49 is in condition for allowance or appeal.

Respectfully submitted,

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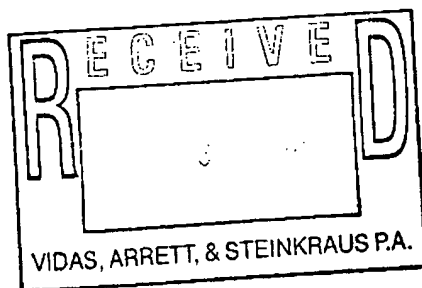
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INTERVIEW SUMMARY

All participants (applicant, applicant's representative, PTO personnel):

(1) Corrine McDermott (3) _____

(2) Jonathan Grad (4) _____

Date of Interview 12/18/03

Type: ☐ Telephonic ☐ Televideo Conference ☒ Personal (copy is given to ☐ applicant ☒ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No If yes, brief description: _____

Agreement ☐ was reached. ☒ was not reached.

Claim(s) discussed: 34

Identification of prior art discussed: Art of record.

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: _____

Discussed rejection of Parker, not clear how it is inherently more fusible because of the larger diameter. Proposed amending claim to overcome rejection of Hankh by more specifically pointing out terminal ends, to overcome objection by deleting "continuously". The

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

☐ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary. A FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

Examiner Note: You must sign this form unless it is an attachment to another form.

antecedent basis objection is not necessary, claim is understandable.